PLANNING TRIALS USING DIGITAL TECHNOLOGIES

Following are opportunities for patient and site input that are unique to, or important for, planning clinical trials that use digital technologies for data collection. Patient and site input should be sought early and often.

TOPICS FOR PATIENT & SITE INPUT INCLUDE:	
 SELECTING OUTCOME MEASURES	Focus on measures that are meaningful to patients. Select a technology-derived assessment only if better (e.g., more meaningful to patients or more informative) than existing outcome assessments. See CTTI Recommendations for Developing Novel Endpoints
 DEFINING STUDY PARTICIPANT CHARACTERISTICS	Develop plans for participant inclusion and diversity, and identification of opportunities and risks related to technology access and literacy. See CTTI's considerations for engaging patients
 SELECTING DIGITAL TECHNOLOGIES	Weigh protocol elements against added participant burden; evaluate the acceptability, usability, and tolerability of digital technologies; and plan for participant expectations. See CTTI Recommendations for Selecting & Testing Digital Health Technology As necessary, test digital technologies with sites and a representative patient population. See CTTI's considerations for selecting digital technologies and planning
 PLANNING TRIAL LOGISTICS	Identify and develop plans for addressing technical support needs of participants, as well as facilitating patient-site interactions. See CTTI's considerations for minimizing participant burden Identify and develop plans to address challenges for investigative sites, including budgets and contracting, infrastructure, training, and technology malfunctions. See CTTI Recommendations for Supporting Sites
 DEVELOPING STUDY MATERIALS & COMMUNICATIONS	Seek input on informed consent materials, including specific considerations related to data and health monitoring, health and technical literacy, and patient privacy and confidentiality Evaluate opportunities to return outcomes and other data, and determine how best to return value to study participants. See CTTI's considerations for maximizing value for study participants

Resources that provide a broader examination of opportunities to engage stakeholders in the clinical research process include the CTTI Quality by Design Toolkit, CTTI Patient Groups & Clinical Trials Recommendations , PCORI Engagement Rubric, and NCATS Toolkit for Patient-Focused Therapy Development.